DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#17

Re: Fareston®
Docket No.: 97E-0357

JUL 24 1998

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,696,949, filed by ORION-YHTYMA OY, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Fareston®, the human drug product claimed by the patent.

The total length of the regulatory review period for Fareston® is 3706 days. Of this time, 2828 days occurred during the testing phase and 878 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: April 8, 1987.

   The applicant claims March 17, 1987, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 8, 1987, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: January 3, 1995.

   The applicant claims February 3, 1995, as the date the New Drug Application (NDA) for Fareston® (NDA 20-497) was initially submitted. However, FDA records indicate that NDA 20-497 was submitted on January 3, 1995.

3. The date the application was approved: May 29, 1997.

   FDA has verified the applicant's claim that NDA 20-497 was approved on May 29, 1997.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis, R. Ph.
Deputy Associate Commissioner
for Health Affairs

cc: Ronald J. Kubovcik
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